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We have shown that convective air warming device (e.g., "Bair Hugger") is feasible for cold weather conditions and aeromedical evacuation. The goal of the project was to develop such a device that can keep patients warm in 0°C conditions and can run for 2 hours using battery power. Our testing showed that with appropriate insulation and recirculation of warm air from within the device, as little as 250W was needed for adequate function. Using this information, we built prototype heating units and coverlets that made efficient use of available battery power. The warming coverlet was designed as a disposable sleeping bag that fully encloses the patient but still allows easy access for medical treatment. The heating unit attaches under a standard litter and readily adapts to available power sources (110 VAC, 24 VDC, and battery). Testing with volunteers verified that the system was well able to meet requirements. Therefore it could follow a patient from forward medical facilities, through ground and helicopter transport, post-surgical waiting, and finally through evacuation on military aircraft. It is also compatible with existing Bair Hugger surgical blankets. Civilian uses for the same technology are planned, specifically medical transport and outdoor rescue.

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I. Summary

Hypothermia can have profound negative effects on seriously injured patients, and the U.S. Military has identified hypothermia is a major problem during the aeromedical evacuation of wounded soldiers from Iraq. The aim of the project was to investigate the use of convective forced air warming to prevent hypothermia in patients who have suffered battlefield trauma.

Arizant has used this method for over 10 years in civilian clinical settings (e.g., the “Bair Hugger” system), but has never applied it to the extreme conditions encountered in military aeromedical transport. The project solicitation requested a portable device that keeps patients warm in 0°C conditions and can run for two hours using battery power. Our goal was to determine if this was feasible.

We are pleased to report that the requirements of the solicitation are readily met with battery powered convective warming technology that was developed over the course of this project. During Phase I we constructed an environmental test facility that allowed us to specify the energy requirements needed to keep patients warm in cold-weather conditions. The testing showed that with appropriate insulation and recirculation of warm air from within the device, as little as 250W was needed for adequate function. Using this information, we built prototype heating units and coverlets that made efficient use of available battery power. Testing with volunteers verified that the system was well able to meet requirements.

Our device is intended to prevent casualty hypothermia both outdoors and during aeromedical transport. The warming blanket is designed as a disposable sleeping bag that fully encloses the patient but still allows easy access for medical treatment. The air-heating unit attaches under a standard litter and readily adapts to available power sources (110 VAC, 24 VDC, and battery). Therefore it could follow a patient from field medical facilities, through ground and helicopter transport, post-surgical waiting, and finally through evacuation on military aircraft. It is also compatible with existing Bair Hugger surgical blankets. Civilian uses for the same technology are planned, specifically medical transport and outdoor rescue.

Arizant pioneered the treatment of hypothermia during surgery and now ships over 10 million warming blankets a year worldwide. We have a strong track record of inventing and commercializing new medical products. If favored with a Phase II grant, the company would vigorously pursue development of this product, preparing it for testing in about one year’s time, after which it can be field tested in forward deployed environments.

II. Introduction

Hypothermia in Battlefield Trauma Patients

In the last decade numerous studies have documented the adverse effects of hypothermia on surgical patients. They include: wound infection¹, hemodynamic stress², cardiac disturbance³, coagulopathy⁴⁻⁷, prolonged and altered drug effect^{8,9}, increased mortality^{2,10}, shivering, pain and thermal discomfort. It is well established that hypothermia is a dangerous complication in normal surgical patients.¹¹ It slows healing, produces pain, and lessens the chance for a successful outcome. In battlefield settings hypothermia is recognized as a significant clinical challenge in critically injured patients.

The Navy has stated that the improvement of combat casualty care is a high priority for its ongoing research. Specifically, the following is identified as a first priority:

“In FY 2004 and FY 2006: Reduced metabolism - lengthening trauma casualties’ Golden Hour”¹²

To this end, hypothermia has a direct and profound effect on the survivability of battlefield trauma victims. The severity for battlefield injuries is worsened for several reasons:

Extreme environments. Military personnel are more likely to be injured while working in extreme environments. DeGroot has done a comprehensive survey that found that hypothermia is a common injury for soldiers.¹³ Hypothermia can and does occur even in warm regions of the world such as the Middle East.^{14, 15}

Minimal resources. The injuries can be severe but the means to treat them in the field are minimal. The resulting exposure makes hypothermia more likely to occur. Trauma is difficult to treat even for experienced clinicians in well-equipped settings. Bowley stated:

The operating theatre is a hostile and physiologically unfavourable environment for the severely injured patient. Laparotomy for major trauma involves dissipation of heat and massive blood loss requiring replacement. The result is a vicious cycle of hypothermia, acidosis and coagulopathy leading to death from an irreversible physiological insult.¹⁶

Extended exposure. Due to the obvious difficulties of field conditions, the time between injury and treatment is frequently extensive. A wounded soldier lying on the ground, partially unclothed, and exposed to a harsh environment will be at great risk for hypothermia.

The Unmet Need for a Transport Warming Device

While clearly an unmet need, devices for transport warming have not received the attention given to clinically based devices. Commonly available wool blankets have very poor insulation properties, as shown by our experiments. Reflective mylar “space blankets” are inexpensive and portable, but do not function any better than ordinary blankets or even plastic sheets.¹⁷ The Norwegian army has developed a device for outdoor cold-weather rescue.¹⁸ It uses burning charcoal and a small fan to pressurize a manifold of small hoses. Few reports are available on how well it functions. Several portable resistance-heating blankets have recently come onto the market.^{19,20} Both of them work like conventional electric blankets, except that they provide a battery pack for field use. At present, neither device has been validated by field use.

Comparison of convective versus conductive warming methods

There are a number of conductive warming systems that compete with convective warming in the medical marketplace. These may take the form of “water mattresses” that use a multitude of small tubes to circulate warm water close to the patient’s skin and “electric blankets” that use electrical resistive wiring to achieve

the same purpose. Typically electric blankets operate at low power levels (15-20 watts). While such systems might appear attractive for aeromedical evacuation because of small batteries and modest weight, there are serious drawbacks for this application. We want to specifically address the inadequacies of these kinds of devices, and explain why we chose the convective method when an electric blanket would, in many ways, be easier to design.

1. *Temperature uniformity.* Our experiments have shown that water mattresses and electric blankets rarely provide adequately uniform heating. Because the heat source in the coverlet is typically localized, in the form of a tubes or wires, they comprise the active warming area of the blanket. The actual heated surface area is thus quite small, with a corresponding reduction in uniformity.²¹
2. *Control.* For electric blankets when the heat load is not totally uniform, a global control sensor is inadequate, resulting in hot spots that are too hot to be safe, and cool-spots that are too cool to be effective.
3. *Contact resistance.* Thin layers of fabric and small air gaps create “contact resistance” that drastically reduces the rate of the heat transfer²². In fact, most conductive devices work primarily by heating the nearby air: the same mechanism as convective warming, but with less efficiency because the air under the blanket is static.
4. *Thermal loading.* Low-power conductive devices cannot maintain effective temperatures while under thermal load.²³ The cool body and surrounding environment quickly draw heat away from the coverlet faster than the power supply can replenish it.
5. *High cost of coverlet.* Coverlets with embedded wire or tubes are expensive to make; some developers have made them reusable for this reason, others accepted the high price and labeled their device for single patient use only. The civilian marketplace has strongly favored disposable coverlets because of the inconvenience and cost of cleaning reusable blankets.
6. *Risk of pressure injury.* Conductive warming devices are frequently designed such that patients lie directly upon the heating element. This can greatly increase the risk of pressure sores.^{24, 25} This risk is exacerbated by the long durations encountered in aeromedical transport.
7. *Safety.* Water mattress and electric blankets have a published record of causing burns.^{26, 27} Convective warming systems have been used safely for over ten years, with no published reports of injuries.

We have discussed this issue at some length because it is important for the selection of an appropriate method for this application. As a company, Arizant has had many opportunities to evaluate conductive warming systems and always rejected them for one or more of the reasons above. Our successful record with convective warming technology is the reason we chose it for this proposal.

III. Methods

Scientific/Technical Objectives and Approach

Having identified the need for military rescue warming, we sought to achieve the following goals. A detailed description of the work performed during the grant period is conveyed in Appendix 1.

1. **To demonstrate that convective warming is efficacious in cold ambient environments (0°C).**

We developed a mathematical model describing the heat transfer associated with cold-weather use of convective air warming. This helped to identify and bound important factors that affect how well the technique works. We then constructed an environmental



Figure 1. Environmental test chamber.

chamber that simulated conditions found during military aeromedical transport, and also an instrumented manikin that allowed careful measurement of the simulated human body energy balance under various conditions. Our testing showed that common patient coverings (wool blankets and the like) have notably poor insulative value – it is not surprising that patients become hypothermic under such conditions. Other coverings with passive insulation (i.e., down sleeping bags) fared better, but still were insufficient to overcome the large amount of heat lost to the cold environment.

“Active methods” (i.e., methods that use warmed air) were found to shift the energy balance in favor of the patient, as long as coverlet insulation was sufficient, and air leakage was controlled. The best design tested reduced net heat losses to below 80W, the level that a sedentary individual’s metabolism can supply. After taking account of various losses within the system, we concluded that such a system would function adequately using 250W – an improvement over the 1400W required by standard convective warming devices. On this basis, we have concluded that convective air warming feasible for cold weather applications.

2. To identify and assess potential energy sources for heating air in the following venues: outdoor rescue, ground vehicular transport, and aviation transport.

We originally believed that the power needed to warm patients in cold-weather conditions would be much higher than that required for indoor clinical applications. Pursuing this line of thought, we examined a number of heat sources possessing high energy density. We had envisioned a system of detachable, modular heat generators: electrical resistance heating for when electricity was available, and some high-energy-density heat sources for outdoor stand-alone use. Assuming this large energy requirement, battery power was believed not to be an option because of excess weight. All of the options we considered were based upon regulating high-temperature gases (greater than 100°C) with the *direct contact rotary heat mixer* (DCRHM) concept presented in our grant application. This device mixes cool ambient air with an incoming hot air stream to provide any desired temperature, providing an efficient means to control the temperature of an unregulated heat source.

A few of the proposed heat sources were interesting, and might perhaps hold merit for other uses. First was the use of air already warmed by vehicle heating systems, collected from nearby ventilation outlets. While effective, we doubted this concept would be practical in actual use. Second was magnesium galvanic corrosion, a chemical reaction already used for rapid warming of fluids in military products. Third was propane catalytic, a form of combustion facilitated palladium catalyst. No open flame is present but very high temperatures can be achieved with minimal fuel use. The problem with the latter two options was concern about toxic emissions within enclosed spaces. While we intended these methods to be used only outdoors, with adequate ventilation, we could not guarantee that this restriction would be followed in the field. Also, the airworthiness of such systems is unknown.

Fortunately, the results of our research showed that a large energy requirement was unnecessary for well-insulated coverlets. A modestly sized battery would, in fact, be sufficient to power a convective warming device. The exact balance between cost, weight, and run time is an open question, but we have found that 2 hours is easily possible with less than ten pounds of battery weight.



Figure 2. Prototype coverlet.

3. To build proof-of-concept heat exchangers for the warming unit that use the energy sources outlined in Objective 2.

Our research has shown that the key to making convective air warming work in cold environmental conditions is to conserve as much heat as possible. This may be accomplished by adding a layer of insulation to the coverlet, an arrangement that still entails a considerable energy cost to heat the cool ambient air to a suitable temperature. A second strategy is to reduce the energy needed for heating input air by recycling previously warmed air from within the coverlet. Because much of this air would otherwise be lost to the environment via leakage, this strategy further reduces the net power input required for adequate functioning.

In order for the concept of recirculation to work, the fluid flow resistance at various points within the system must be tailored to insure that the coverlet is fully inflated, while still providing a robust air stream to the patient. This was achieved in a series of prototype coverlets where recycled air returns to the heater by way of an inlet hose. We found the best design was a fully enclosed “sleeping bag” design. This coverlet provides a large warm interior space enveloping the patient. By situating the inlet hose between the patient’s feet, the temperature of the inlet stream was maximized and a beneficial circulation of air within the coverlet was maintained.

Overall, the benefits of recirculation increase as the ambient temperature becomes lower. We estimate power savings of 25% at room temperature and 77% at 5°C. This improvement is appreciable and adds considerably to the feasibility of the device.

4. To build proof-of-concept prototype warming units that use the heat exchangers outlined in Objective 3.

Building on our many years of experience in the medical device arena, we knew that a well designed and constructed warming unit for aeromedical evacuation must have a high degree of usability, can be easily stored and maintained, is portable and rugged, and the warming units are capable of running for two hours with available battery power. With little other guidance, we constructed a warming unit that is only one possible way meet these requirements.

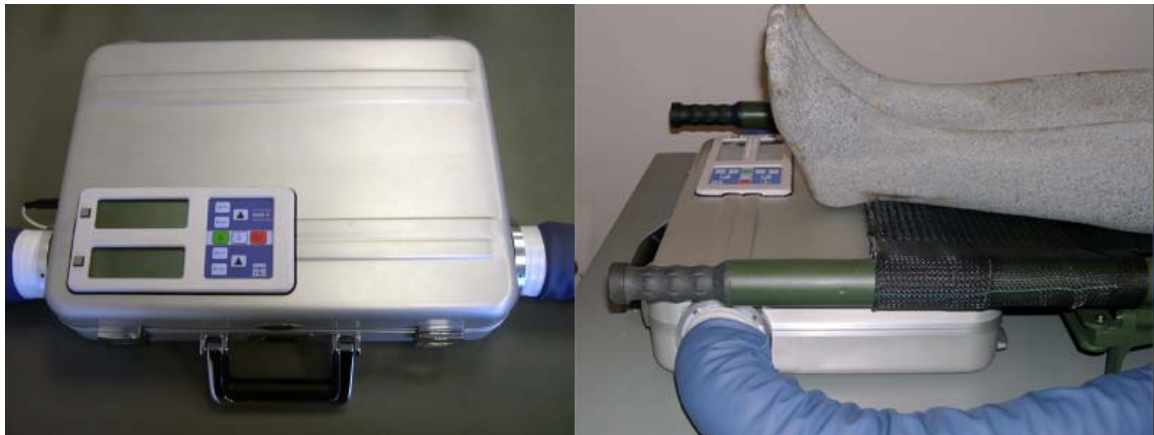


Figure 3. Prototype warming unit.

The prototype warming unit shown in Figure 3 is the size of a briefcase and is designed to be hand carried or attached to underside of standard litter. It includes of a blower, heating elements, control circuits, and batteries all contained in a robust case. In addition to high-tech lithium-ion-polymer batteries, the unit operates on 110VAC or 24 VDC electrical power. The AC and DC parts of the circuit are fully independent and redundant so that if one fails or is damaged, the other will still function. Also included is a two-channel patient temperature monitor with displays on the outside of

the case. Using this system, the medic can both warm the patient and assess how well the warming therapy is working.

There are two air connections on the device. The “air out” port transports warm air to the patient via a short insulated hose. The “air in” port can receive either ambient air, or to increase efficiency, may be connected to a hose used to recirculate warm air. Within the unit, internal airflow is used to cool the batteries and electronic components, thereby boosting energy efficiency by conveying otherwise wasted heat to the patient.

To add flexibility to the device, we have designed it to provide both hypothermia prevention and hypothermia treatment. The first mode, hypothermia prevention, uses the highly insulated coverlet described above, and works with any power source. This is possible because of the relatively modest power requirements needed to overcome heat loss. A much greater amount of power is needed to reverse hypothermia that has already occurred. Accordingly, only AC power can be used in the “therapeutic mode”. Because the warming unit has this high-power setting, it can be used, if necessary, as a conventional Bair Hugger during surgery (Figure 4). To make this more convenient, our unit is designed to accommodate all available Bair Hugger blankets as well as the new insulated coverlet.



Figure 4: Unit operating with a full body Bair Hugger convective blankets.

Many of our design choices are necessarily provisional. For example, we chose to use lightweight but expensive batteries. If cost were an issue, we might have chosen less costly lead-acid cells, with a substantial penalty in weight. In the area of performance, we chose a power level that we judged to be adequate for the majority of cases in which the device might be used (see #5 below). It may be expected that users will have differing opinions about these choices, and Phase II will no doubt involve a detailed analysis of cost, performance, weight, durability, and ease of use.

5. To compare the design and performance of the prototype warming units to requirements gathered from the project monitor and expert users.

The project solicitation cited specific required performance levels:

- Prevent hypothermia outdoors at temperatures greater than 0°C
- Prevent hypothermia in military aircraft at temperatures greater than 10°C
- Operate for two hours under battery power
- Include a patient temperature monitor
- Airworthiness certification

This list, while helpful, was not sufficient for our purposes. We needed to know more about the conditions that accompany military evacuations that strongly influence heat loss in cold weather conditions. Primary among these is wind speed, degree of patient covering, and local radiant temperature*. We have determined these variables as best we can and summarize them in the Table 1 (page 9).

Wind speed is a major factor for the outdoor and helicopter use cases. Body coverage is also important, both for preventing escape of warmed air and also for preventing undue radiative losses. For modeling purposes, we assumed that patients would be almost entirely wrapped, with only the head exposed. Radiant temperature is easy to identify in some cases: room temperature (25°C) for indoor and ground vehicular cases. The radiant temperature of a sunless sky varies between -40°C to 0°C depending on cloud cover. The interior wall temperature of military aircraft is reputed to be quite cold; this depends on weather and altitude, but we assumed it to be roughly -10°C. All of these factors are subject to confirmation, but we assume they are reasonable.

Other guidance we received from military medicine specialists was useful and revealing. We were told to make the device rugged, of course, and flexible in how it could be used. A consistent theme from seminars and discussions was that military medical devices be multifunctional: the more different ways a piece of equipment can be used, the more good it will do. It should also readily interact with standard military equipment (especially litters), and we made a particular effort to determine how patients are transported and positioned during aeromedical evacuation. Accordingly, we believe our prototype represents a viable concept that will serve as a starting point for future refinements.

6. To document final specifications for Phase II design work. (Phase I Option)

If favored with a Phase I option grant, we will use this interval to make contact with potential users of our device and formalize the discussion of detailed specifications. Specifically, we will determine if our assumptions about the various use cases are valid, and collect opinions about how best to configure the final product. Another part of this effort will be an initial pro forma business model that includes accurate estimates of cost, price, and market size.

IV. Discussion

Results

We have shown that convective air warming is feasible for conditions relevant to military use. Our mathematical models for heat loss were well validated by environmental and volunteer testing. This allows us to optimize the final device for the actual conditions it will encounter. This is an important result because the range of conditions is potentially quite large. The main challenge is to provide sufficient energy to overcome heat losses to the environment without having to oversize the battery or make undue demands on available power supplies.

In order to put bounds around the problem, we have identified five “use cases”, each with associated environmental conditions.

The most challenging situations are the “Outdoor” and “Helicopter” cases. Here moderate wind speed and low radiant temperature combine to rapidly cool a patient in this setting. Addressing the heat loss is made

* Radiation heat transfer depends on the temperature of the patient and the temperature of objects to which the patient is exposed: walls, ceilings, ground, and sky. The average temperature of the objects to which the patient is exposed is designated as the “radiant temperature”. In many cases radiative heat transfer is negligible, but in environments important to this project radiative heat loss can be substantial and even dominate other mechanisms.

more difficult by the requirement for portable (battery) power. These cases drove our design toward greater energy efficiency rather than toward exotic power sources.

Table 1. Military Warming Use Cases

Parameter	Aircraft	Outdoor	Indoor	Ground Vehicular	Helicopter
Ambient air temperature	10°C	0°C	20°C	15°C	10°C
Radiant temperature	-10°C upper 20°C lower	0°C upper 10°C lower	20°C	15°C	0°C
Body Coverage	95%	95%	95%	95%	95%
Wind speed	0.7 mph	1.1 mph	0.7 mph	0.7 mph	10.0 mph
Available power source	110 VAC	24 VDC battery	110 VAC	24 VDC	24 VDC
Power requirement 250 W system*	79 W	250 W	0 W⁺	41 W	271 W

The next most difficult case is “Aircraft”, the case of greatest interest to our contracting agency. Here, the radiant temperature of the cold aircraft inner wall increases heat loss. Fortunately, line power is available, but we are conscious of not making excessive demands on the aircraft’s power system. We believe that the power required per patient is not excessive. The other cases, particularly “Indoor” and “Ground Vehicular” are easy by comparison, making small demands for power, with external power sources readily available.

The last line of the table, “power required”, is an estimate of warming unit power needed to balance heat losses and prevent hypothermia when the prototype warming system is being used. The actual wattage value is specific to the listed operating conditions. However, practical tests showed that the predicted power requirements of Table 1 are quite close to real-world values (Table 2). This close agreement validates our computational model and provides confidence in its further use.

As noted above, the outdoor case is problematical because it represents the harshest combination of environmental conditions. In particular, the effectiveness of any warming device will necessarily depend strongly on wind speed. This is because convection is a very effective means of removing heat from any warm object. Figure 5 is a graph that displays the performance of our prototype device under outdoor conditions. The figure shows that our prototype device can function effectively above 10°C even in moderate winds. Effective performance below 5°C requires calm conditions. As shown above, the requirement for the outdoor case (271 W) exceeds the current capacity of the prototype system (250W). It is possible to extend the effective range to more extreme conditions, but at the cost of greater weight and expense. This is a classic engineering tradeoff that requires research and compromise to find a proper balance.

* Calculated power requirements are for our final prototype coverlet: bottom is ½” Thinsulate, top is convective warming blanket, ½” Thinsulate, and aluminized Mylar. Also assume 70% recirculated air. The metabolic heat generation of the patient is assumed to be 80 W..

⁺ The indoor case requires no power from the warming unit because the insulation is effective enough to retain the patient’s own metabolic heat. This would not be the case, however, during surgery, where a sizable amount of skin surface is exposed to the environment.

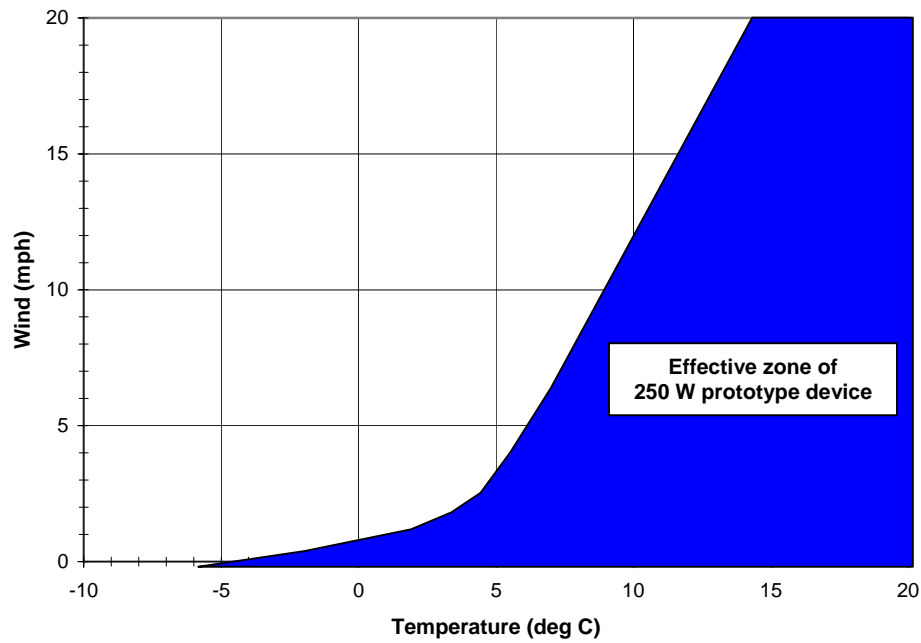


Figure 5. The effectiveness of our prototype device as a function of ambient temperature and wind speed (Outdoor use case). The blue area is the effective operating zone of a 250 W device.

Table 2. Results of Practical Tests

Trial	Case 1	Case 2
Location	Inside a garage	Outdoors on a cold Minnesota day.
Ambient air temperature	7.6°C	-6 °C
Radiant temperature	15 °C upper 5 °C lower	-15 °C upper -6 °C lower
Body Coverage	95%	95%
Warm Air Recirculation	70%	50%*
Wind speed	Calm	Calm
Predicted power requirement	94 W	341 W
Actual power requirement	91 W	300 W

* Two different prototypes were used respectively for case 1 and 2; hence each had a different ability to seal around the patient. During testing, we qualitatively found that the prototype used in case 1 provided a better seal, producing a recirculation estimate that was 20% greater.

The results displayed above are based on a combination of analytical modeling and test results from an instrumented manikin. In order to validate our assumptions, it was important to test our device with real people under real-world conditions. We chose to use healthy non-anesthetized volunteers. This is not a perfect representation of reality, but we can approximate the desired thermo-neutral state by assessing thermal comfort. (If the subject is thermally comfortable, he or she is probably not gaining or losing heat.) Past studies on non-anesthetized persons suggest that skin temperature drop must be limited to a very narrow range to achieve thermal comfort (about 1-2°C), and that this range is probably several degrees greater than the thermo-neutral point for an anesthetized individual²⁸. However, this difference is likely to be small compared to the many other large uncertainties encountered in the field environment.

These practical tests were done using the final prototype system, both outdoors under calm conditions, and indoors. The test subjects were allowed to adjust the power setting of the unit until they were thermally comfortable. In this way, we determined the energy balance and actual power requirements under a given set of conditions, independent of any assumptions. The results showed a gratifying agreement between the analytical predictions and the tests (Table 2). This table shows a very good agreement between analytical and test results that gives confidence that our models are valid and that we can continue product development with confidence.

Conclusions

The research performed for this project accomplished its goal: to demonstrate that convective forced air warming is effective for conditions relevant to the evacuation of battlefield casualties. A combination of analytical modeling and laboratory testing showed this technique is feasible in cold ambient conditions.

Our conclusion is based the following:

- We considered five basic use cases encountered during military evacuation: aircraft, outdoor, indoor, ground vehicular, and helicopter. Each use case has its own set of environmental conditions.
- The aircraft and outdoor use cases are of particular interest to our sponsors. Special attention was given to these cases.
- In an aircraft, passive insulation is insufficient. Wrapping with a wool blanket reduces heat loss from 439 W to 201 W, but this loss is still too great to be compensated by metabolism (80W). Active warming is needed to bring the loss to acceptable levels.
- We calculated that a system power of 250 W is sufficient to keep a patient warm within a normal military aircraft at 10°C, and also outdoors at 0°C under calm conditions.
- This power requirement is easily met with a portable convective warming, battery-powered device. We built a prototype of this system using a specially designed blower and a lightweight, high-tech battery. The present unit weights 25 pounds.
- Experiments showed that the power required to run the prototype closely matched analytical predictions. While drawing the maximum power of 250 W, the system will run for over two hours. Under conditions of the aircraft use case, the power draw is 91 W. In this case, the run time is over six hours.
- We identified values for insulation, radiative loss control, and warm air recirculation needed for successful operation of the convective warming device.

There are yet some unknowns to be quantified, but they will be investigated in Phase II. It remains to test the system on anesthetized humans under actual field conditions. There are still many choices to be made about the design of the final product. However, we see every reason to proceed with developing this device for military and civilian markets.

Recommendations

Arizant, Inc. is well positioned to continue development of the Patient Warming Device through the execution of the Phase I option, and an invitation to submit a SBIR Phase II proposal. During the SBIR Phase I option, Arizant will make contact with potential users of our device and start the discussion of detailed specifications. Specifically, we will determine if our assumptions about the various use cases are valid, and start to collect opinions about how best to configure the final product. Another part of this effort will be an initial pro forma business model that includes accurate estimates of cost, price, and market size. In Phase II, we will complete the final design of the system and perform in-flight tests.

V. Potential Applications

Military

We have already discussed the five use cases we are trying to serve: aircraft, outdoor, indoor, ground vehicular, and helicopter. It is our intention to design this device to operate in all of these environments. The need for such a device is apparently large, both in importance and in numbers.

The ability to treat hypothermia far forward in the battlefield has been identified as a first priority to improving combat casualty care by the Office of Naval Research.²⁹ This strong interest in hypothermia prevention indicates that a sizeable market may exist. Additionally:

- There were 45,524 medical transports from combat areas between 9/11/01 and 1/24/2004. Of these, 3,426 were classed as urgent.³⁰
- Air Mobility Command reports 1,650 scheduled and 350 unscheduled aeromedical evacuation missions each year³¹
- 43% of these flights were to Germany, and 23% were to the US. The total mission time in such cases was 15.7 hours.²⁵
- There are 31 aeromedical evacuation squadrons in the Air Force (four active duty squadrons with 98 total aircraft).²⁶
- 87% of all aeromedical evacuation forces are from the Air National Guard or Air Force Reserve Command.²⁶
- 3,200 AE missions have supported worldwide patient movements through the AMC Global AE system in the past year. This includes, but is not limited to, Global War on Terrorism support.²⁶

It is difficult at this time to estimate the actual demand for the device. It would depend on a number of unknowns: How many squadrons/units will have a desire for it. How many systems would each squadron need? How many coverlets would each use on an annual basis? It is clear that market demand would fall into two categories: the initial “stocking up”, and subsequent ongoing demand. We will need to investigate this closely during Phase II

Alternate uses for the system are possible. We do not yet know if it would be suitable for immediate treatment of injured soldiers during combat, but our impression is that hypothermia prevention is a secondary concern under these conditions. While the funding agency of this project is the Navy, it appears that the Air Force could also be a major customer of this device.

Civilian

The primary civilian use for our proposed device would be emergency ambulance transport.

- The US civilian market experiences 15 million emergency ambulance trips a year, growing at a rate of 4.7% annually.³²

- Of these, roughly one third are due to outdoor trauma (mostly automobile accidents). Not all of these accidents occur during cold weather; we estimate the remaining fraction as 1 to 2 million patients at hypothermic risk.
- A rural trauma patient could spend 75.7 minutes between the accident and being seen by a physician in the ER. Of this time, 60.2 minutes will be under the care of a paramedic, and thus treatable with comfort warming.
- An urban person under same circumstances: 59.4 min between accident and ER treatment, 50.5 minutes under paramedic care.³³
- Hospitals frequently perform inter-hospital transports. Although the market size is smaller than that of the trauma market, the need for hypothermia prevention is great. Recent studies have shown that ICU patients have 9.6% greater morbidity rate if transported³⁴ and 11% of patients become hypothermic when transported.³⁵

Based upon these prospective revenue figures, Arizant Healthcare is interested in developing both civilian and military portable warming units. In terms of internal investment, we are able and willing to invest considerable resources into both military and civilian development projects. In addition, added cost savings may be realized because crossover exists between the technologies and designs used for both civilian and military markets. If Phase II funding is received, we intend to have both military and civilian devices commercially available 1-2 years after the completion of our Phase II efforts.

VI. Contact Information

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VII. Appendix

Appendix 1 – Detailed Project Activities

In our proposal we outlined five major goals of the project. They are listed below along with a description of progress to date.

1. To demonstrate that convective warming is efficacious in cold ambient environments (0°C).

Approach

Forced air warming is an effective and safe form of patient warming with over 6 million surgical cases treated in the US last year. Adapting this technology for field use involves changes to two important parameters. The first is the effect of cooler ambient conditions and the second is power constraints for the portable use in the field. Both parameters require design improvements for energy efficiency. Even under normal indoor conditions, the Bair Hugger uses 78% of the input energy simply to bring the air up to the patient's body temperature.

To validate convective warming as a hypothermia prevention therapy for cold weather environments, we needed to determine the following items:

Warming unit hardware:

- Required Airflow (CFM)
- Required Heater Size (Watts)

Convective Blanket Design

- Required insulation
- Range of heat fluxes delivered to the patient
- Heat losses to the environment due to radiation, air leakage, and conduction

Our approach for accomplishing these goals was focused on three major areas: developing a mathematical model for design simulation, building a cool ambient test apparatus, and testing different insulation methods. These tests involved placing a fully instrumented heat flux manikin inside an environmental chamber under cold conditions. The manikin was wrapped in different insulation configurations (mummy sleeping bags, wool blankets, etc.) and convective blanket designs. At the end of this test we had a thorough understanding of which design factors produce the greatest patient heat losses/benefits.

Work Completed

To facilitate the experimental work, a simulated human (a manikin) form was positioned in a specially designed and fabricated wind tunnel capable of providing low-temperature airflows and correspondingly low-temperature surroundings. A schematic diagram of the wind tunnel with the manikin in place is presented in Figure 6. The wind tunnel has cross-sectional dimensions of four by four feet and is 20-feet long. The wind tunnel was, in turn, located in a large, air-conditioned space where temperatures as low as -10°C could be maintained. Air was drawn into the wind tunnel by a large industrial fan situated just downstream of the tunnel exit. The fan was capable of providing airflow having a velocity of about eight miles per hour. All of the walls of the wind tunnel were painted black to provide a controlled environment for radiation heat transfer.

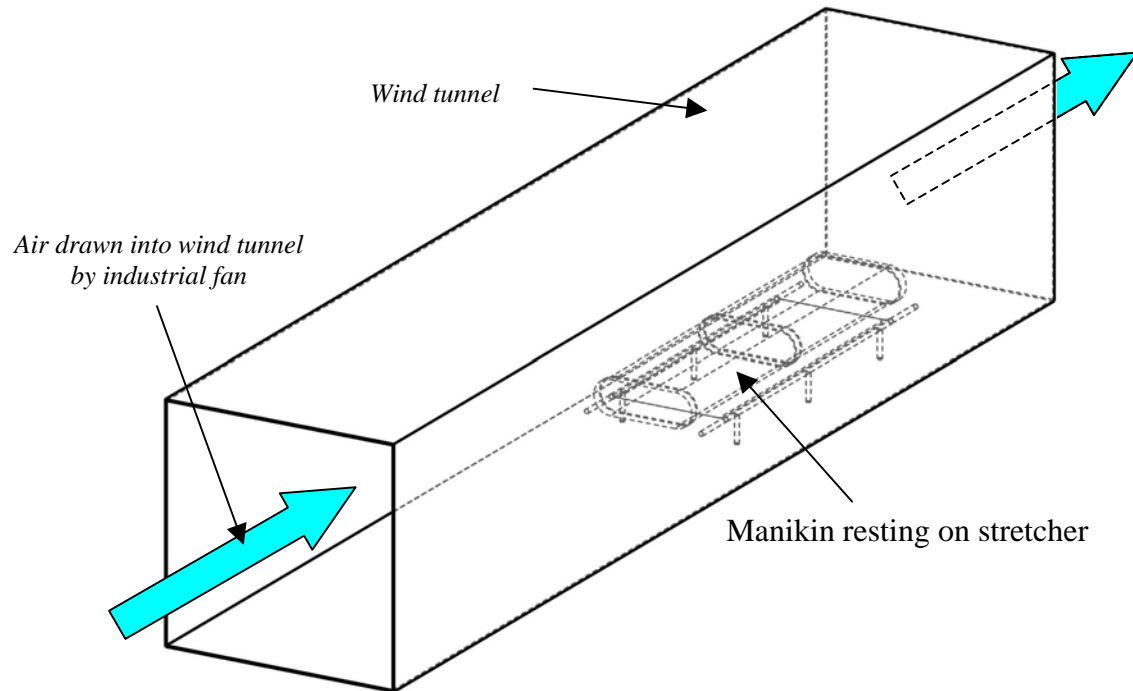


Figure 6. Diagram of the wind tunnel with the manikin in place.

As seen in the figure, the manikin is generally of rectangular shape but with rounded corners. The overall length of the manikin was six feet, with a width of 20 inches and a height of 6.5 inches. It was fabricated from ¼-inch aluminum that was painted black to model the radiation properties of human skin. The heating of the manikin was accomplished by the use of flexible electric heating elements that were bonded to the internal surfaces of the manikin. Electronic controls were put in place so that the power provided to each heating element would produce a uniform temperature of 34°C over the entire exposed surface of the manikin. The high conductivity of aluminum ensured the attainment of temperature uniformity.

The external surfaces of the manikin were instrumented with a total of 22 strategically placed thermocouples. In addition, to enable the determination of local heat losses from the manikin surface to the surroundings, 12 heat flux meters were affixed to the external surfaces of the manikin. The voltages produced by the thermocouples and the flux meters were read and recorded by means of an automated data acquisition system.

Figure 7 displays a representative number of the various thermal management systems that were investigated. All told, 19 different thermal management schemes were employed during the course of the experiments.

Figure 7A defines the simulated exposed-skin situation, while Figure 7B displays the manikin wrapped snugly with wool blankets. An alternative wrapping is shown in Figure 7C. Figures 7B-7C illustrate “passive” methods of thermal management. In contrast, Figures 7D-7E show active thermal management methods. Figure 7D portrays a situation in which the manikin is wrapped with a coverlet through which warm air is flowing (“active insulation”). The setup exhibited in Figure 7E is an example of a very active warming method where by air jets impinge on the surface of the manikin.

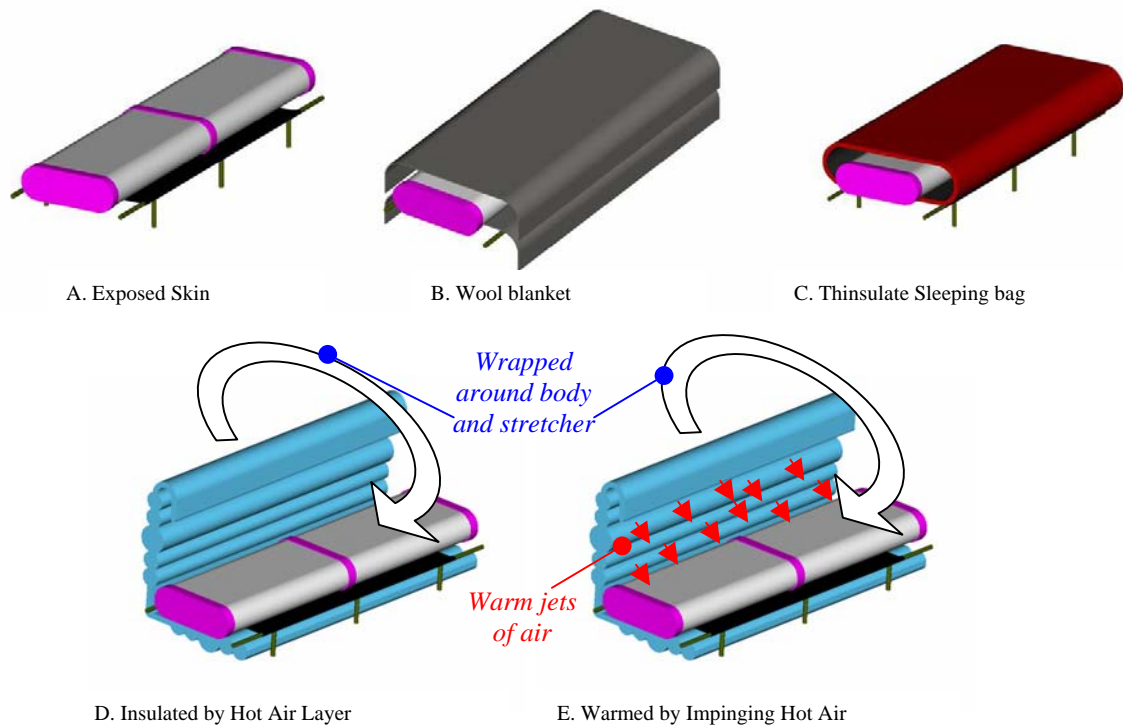


Figure 7. Illustration of the various methods used to diminish skin heat loss that were employed for the experiments.

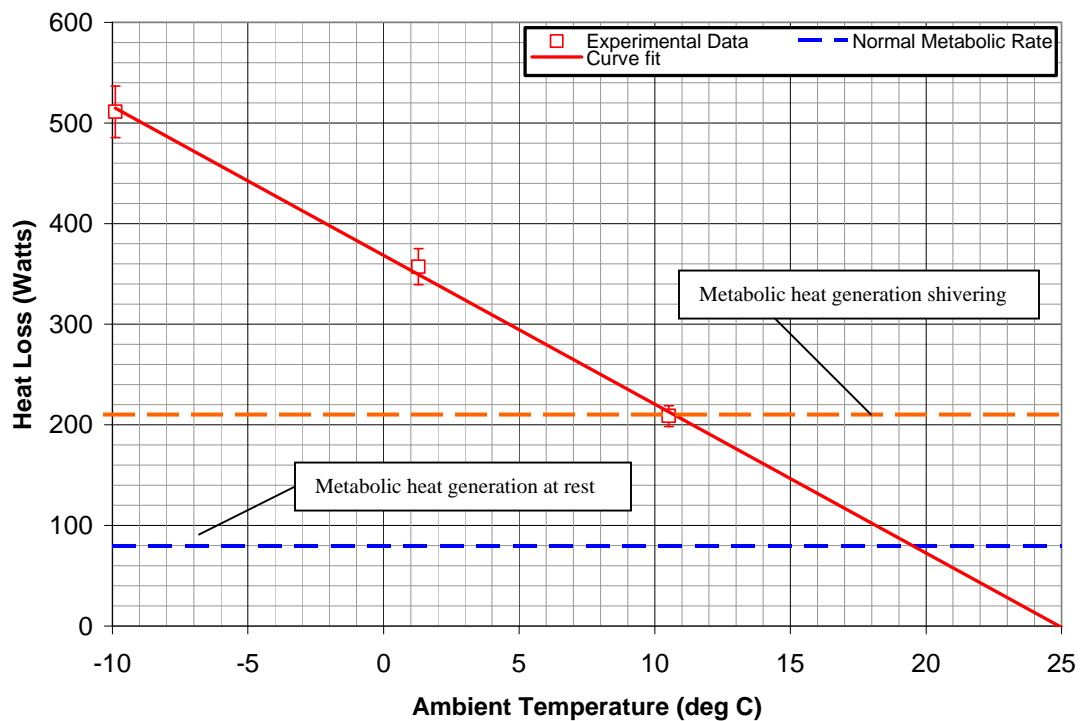


Figure 8. The variation of the rate of heat loss as a function of the temperature of the ambient air for an uncovered manikin.

Figures 8 and 9 present experimental data for the rate of heat loss experienced by the manikin as a function of the relevant operating conditions of the specific tests. In Figure 8, the variation of the heat loss with the ambient temperature is plotted over the range of temperatures from -10 to 25°C. These results correspond to a wind speed of 0.7 miles per hour, typical of the air motions encountered in airplanes used to convey injured soldiers. During the experiments, the temperature of the simulated skin was maintained at 34°C. The temperatures of the wind tunnel walls were virtually equal to that of the ambient air.

Figure 8 reveals a virtually straight-line correlation between the heat loss and the ambient temperature. Such a straight-line variation enables accurate extrapolation to ambient temperatures beyond those that were employed in the experiments. A horizontal line corresponding to 80 watts has been inserted in the figure to show the metabolic heat generation of typical human at rest. It is known from physiology that shivering is the first line of defense that the human body invokes in presence of extreme cooling. However, the additional metabolic heat generation due to shiver, about 200 watts, would be insufficient to cope with the heat losses at temperatures of 10°C and below.

Figure 9 is focused on the effect of wind speed. The green curve shown in the figure is a fit to the data. The experimental conditions for Figure 9 are skin temperature of 34°C, and wind-tunnel wall and air temperature equal to 10°C. The figure shows that the heat loss is very sensitive to increases in wind speed at lower values of speed. However, at larger wind speeds the heat loss increases moderately. Once again, the metabolic heat generation is included for reference.

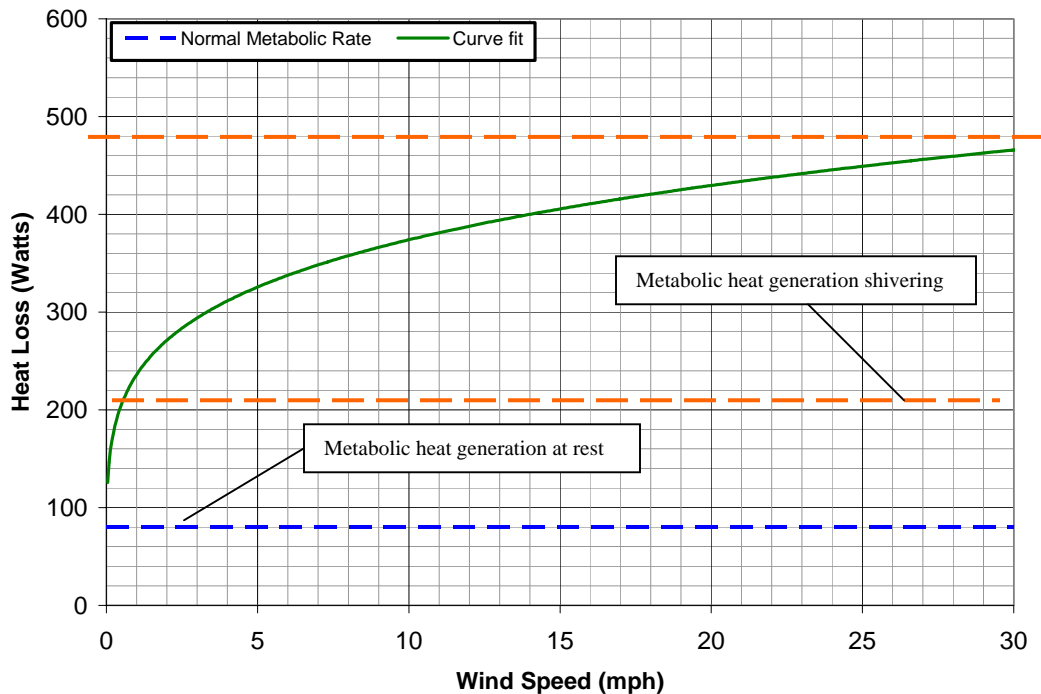


Figure 9. Variation of the rate of heat loss with wind speed passing over the uncovered manikin.

In Figure 10, we compare several schemes of thermal management. These schemes are respectively identified by means of captions situated at the base of each bar. At the very left of the graph, the case of totally exposed skin is displayed. Then, proceeding from left to right, the next three management schemes are passive insulations, whereas the last three correspond to more active methods of management. In general, it is seen that the more active the thermal management, the less is the heat loss. In fact, the rightmost thermal management scheme reduced

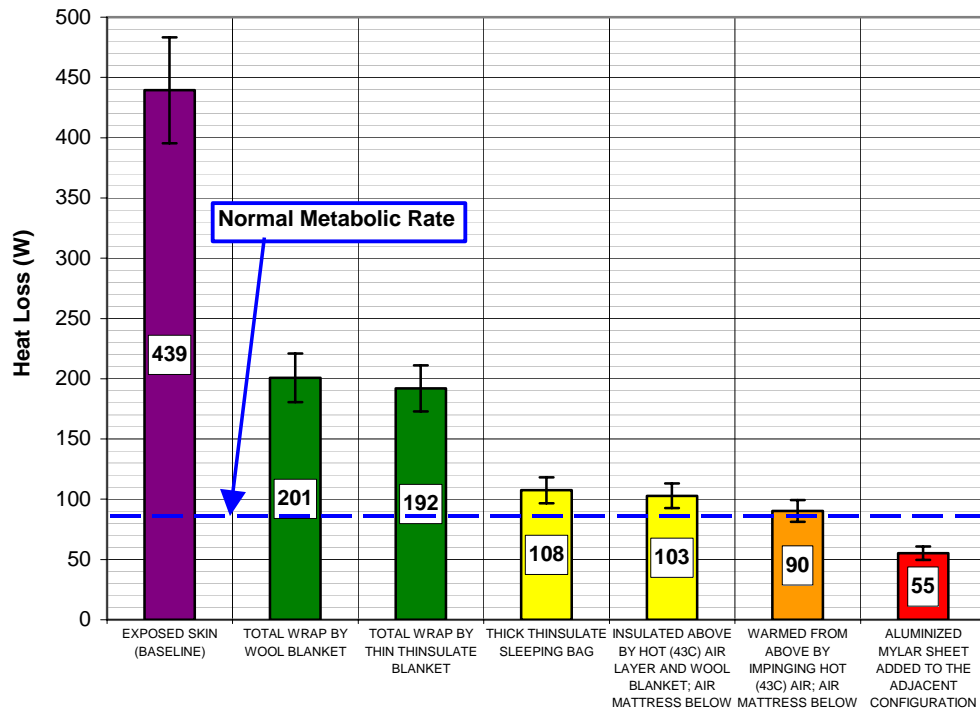


Figure 10. The effectiveness of various thermal management strategies in reducing heat loss

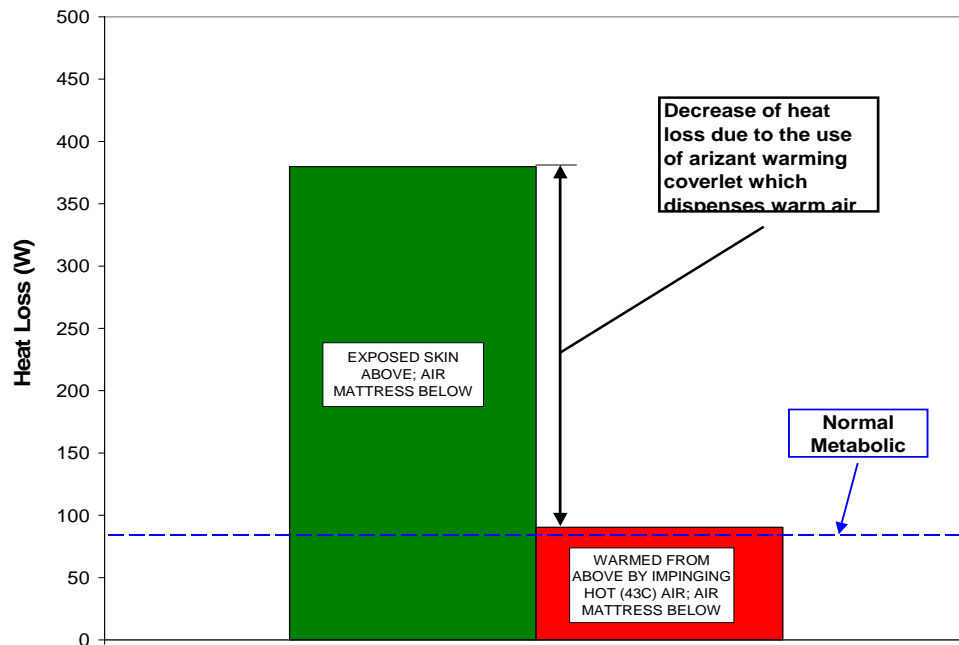


Figure 11: Effectiveness of the Arizant prototype in reducing heat loss.

the heat loss to a level that can be coped with by rest-state metabolic heat generation. In all other cases, the heat deficit would need to be compensated by active warming. The conditions for the results of Figure 10 are skin temperature equal to 34°C, tunnel wall and air ambient temperatures of 10°C, and a wind speed of 0.7 miles per hour.

The effectiveness of Arizant thermal management technology in reducing heat losses is highlighted in Figure 11. That figure displays heat loss results for two cases. For the case represented by the green bar, the topside of the manikin was left fully exposed, while the underside rested on an air mattress. These conditions gave rise to a very substantial rate of heat loss. For the case corresponding to the red bar, the manikin is warmed by air jets from an Arizant full-body coverlet. The figure shows a great reduction in the heat loss by the Arizant device.

2. To identify and assess potential energy sources for heating air in the following venues: outdoor rescue, ground vehicular transport, and aviation transport.

Approach

The implementation of convective warming as a therapy for hypothermia requires the availability of an energy source to heat the air. In this regard, we conducted research to assess the energy sources that are available in the field and in various transport vehicles.

We had originally thought that 1000-2000W of power would be needed to make convective air warming a viable candidate for our purposes. (We later found the actual requirement to be much lower.) Assuming that electrical resistance heating powered by batteries to be out of the question, we sought other power sources to meet the demand. For a candidate to be successful, it must accomplish several functions. First, it must have sufficient energy to heat the ambient air from 0°C to 43°C for two hours. Second, the fuel must be portable in terms of weight and volume. Third, the fuel must not pose a hazard to the operator.

Table 3. Proposed Warming Unit

Parameter	Prevention Mode	Treatment Mode
Air flow rate	16 CFM	40 CFM
Inlet temperature	20°C	20°C
Outlet temperature	43°C max	43°C max
Motor current	0.8 A	0.8 A
Voltage	Internal Battery, 24 VDC, 110 VAC	110 VAC
Battery power	640 watt-hours	-
Blower power	20 watts	20 watts
Total power	250 watts max	1400 watts max
Estimated battery life	160 minutes	-
Battery weight (Lithium Ion polymer)	7.2 lbm	

We assumed that ground vehicles and aircraft would have some form of electrical power source on board. This would be used for long-term (greater than two hours) operation. In the outdoor rescue venue, we did not expect to find an external energy source. Thus the identification and assessment of high-energy-density sources was thought to constitute our greatest challenge.

Work Completed

Rather unexpectedly, our research had shown that conventional electrical resistance heating could be sufficient under cold ambient conditions. (As related elsewhere, proper insulation, recirculation of airflow, and the use of high-tech batteries make this possible.) Accordingly, we had no need for the risky high-energy power sources suggested in our proposal. This is fortunate because the resulting device would be simpler, less expensive, and take less time to develop.

Electrical resistance heating – Battery Power. For a properly designed coverlet, we calculate that about 230 watts of heater power will be needed, along with about 20 watts of blower power. This creates a total need for 250 watts – quite within the feasible range for battery power. Our energy calculations show that the following system is fully sufficient to meet the needs of aviation transport and many of those found in outdoor transport.

We have conducted considerable investigation into available battery types, seeking the one that gives the best performance versus weight for our application. The final prototype uses a lithium ion polymer battery with an extraordinary energy density of 470 Wh/liter.³⁶ This battery does not need to be the final selection, and there are many other factors to consider: cost, lifetime, recharge time, and shock resistance. This issue will be further examined during Phase II.

3. To build proof-of-concept heat exchangers for the warming unit that use the energy sources outlined in Objective 2.

Approach

In the process of considering the energy needs of the entire system, one concept emerged as especially promising: recirculation. Instead of expending large amounts of energy heating cold ambient air, would it be possible to “recycle” some of the warm air that is normally lost to environment. Thus, instead of developing exotic, untested energy sources, we undertook to reduce the need for power to the point where electrical resistance heating appeared viable.

Given our focus on electrical resistance heating, the task of designing heat exchange elements becomes much easier. The only complication was accommodating the requirement for both 24 VDC and 110 VAC power. While we might have chosen to convert the higher AC voltage to DC, this would have required a heavy and expensive power supply. Instead, we chose to design a two-stage filament, one stage for AC and one stage for DC. The rest is straightforward electrical engineering that we will not describe in detail here.

Work Completed

The two important elements of coverlet design we considered are insulation and recirculation. They will be discussed below.

Insulation. To maximize the efficient use of energy, it was important to minimize cooling of the air prior to its delivery to the patient. Without care, it is possible for moving air to lose 10-20°C from the hose and the top surface of the coverlet. We focused our efforts on insulating these areas.

There are many different varieties of insulation. We sought one that would have very low thermal conductivity, low bulk, and low cost. After trying a number of less acceptable alternatives, we found that 3M’s Thinsulate³⁷ readily fills these requirements. The final product may have a different configuration, but our final prototype use 1/2” of Thinsulate on the air supply hose, and 1/2” of Thinsulate above the top coverlet. We found this combination to be acceptable during our practical tests.

As discussed elsewhere, radiation is often a major conduit for heat loss. For this reason, aluminized Mylar was considered for use as the outer layer of the prototype coverlet. Due to its low emissivity (0.04 compared to 0.9-0.95 for wool), this layer will block most heat from escaping via radiation. To illustrate this issue, two example scenarios are presented.

First, imagine a situation where a soldier is waiting outside on a clear, crisp night for a transport vehicle. The soldier is lying horizontally on a stretcher and has only a wool blanket for insulation that covers most (95%) of his or her body. Assuming that the air temperature, sky temperature, and wind velocity are 0°C, -40°C, and 2.24 m/s (5 mph), respectively, the soldier would be losing over 400W of heat. By simply adding the aluminized Mylar, the heat loss from the soldier could be reduced below 350W that would be a modest performance increase of 13%.



Figure 12. Warming coverlet with Mylar outer layer.

Second, consider a scenario where a soldier is lying horizontally in a transport aircraft and is insulated again by only a wool blanket that covers most (95%) of the body. In this venue, the air and wall temperatures are potentially as low as 10°C and -10°C, respectively. Assuming a draft exists with a bulk air velocity around 0.3 m/s (0.67 mph), this soldier would be losing approximately 230W of heat to the environment. Whereas, with the addition of aluminized Mylar, the total heat loss could be reduced to about 160W. Remarkably, this thin Mylar sheet improves the heat retention by 30% in this scenario.

The addition of aluminized Mylar as the outer layer of a warming blanket substantially increases heat retention for many scenarios, especially when radiation is normally a substantial mode for heat loss to the environment (i.e. relatively low wall temperatures, moderate air temperatures, and low wind conditions). Since aluminized Mylar is inexpensive and improves performance, it is recommended that this layer be included in the warming blanket.

Recirculation. As related above, recirculation of warm air is critical to reducing energy requirements of our system. The recirculation scheme is shown in Figure 13. A blower moves air to a heater, and thence to a porous blanket. The inflated blanket distributes the air to a multitude of small openings, where it blows upon the patient. Some of the heated air is lost to the environment through openings in the system, but much is recovered and directed to the blower inlet. An additional quantity of air is pulled into the system to make up for losses. (Note that the patient also contributes additional heat to the system via metabolic warming.)

The energy savings from recirculation are significant. In the case of a 10 °C environment with a sealed convective blanket, a warming unit utilizing recirculation uses only 25% of the power that a

non-recirculating unit requires. With battery power at a premium, this is a necessary design feature.

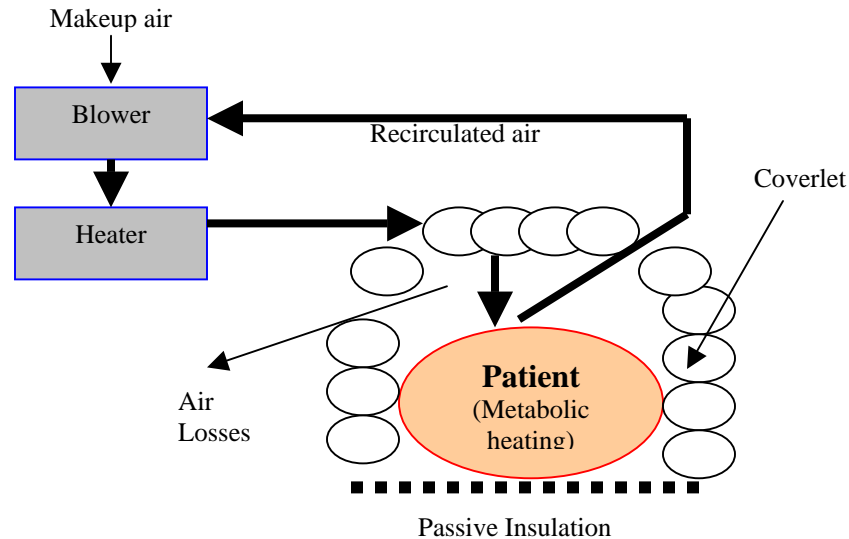


Figure 13: Schematic diagram showing recirculation of scavenged warm air.

4. To build proof-of-concept prototype warming units that use the heat exchangers outlined in Objective 3.

Approach

Having determined the power requirements of the system, we then proceeded to construct a prototype warming unit that incorporates all of the features we deemed necessary for the final device. It was not necessary at this point to have a system that perfectly matched to the user’s needs; this would follow later during Phase II. This version of the device was used to highlight design issues and to assist in real-world testing.

Work Completed

The prototype warming unit is shown in Figure 14. The major electrical and mechanical components are depicted in this schematic. The unit accepts power from 2 external sources, 110 VAC and 24 VDC, and has an internal battery for portable use. As explained earlier, under 24 VDC or battery operation the unit runs at a lower power level providing “hypothermia prevention” – the ability to maintain core body temperature. The primary reason is power conservation. Under AC operation, the unit provides “hypothermia treatment” – the ability to raise core body temperature – and is compatible with both commercial convective blankets and the insulated coverlet. The summarized operating parameters of the two different modes are displayed in Table 3.

Motor and Blower. The unit contains a custom engineered centrifugal blower and a brushless DC motor. The DC motor has an on-board speed control commutation circuit. The complete assembly is shown in Figure 15. This design has worked out well for testing purposes because the air flow can be varied over the range of 0 to 40 CFM by adjusting the commutation circuit. This flexibility has allowed us to establish the unit operating bounds for hypothermia treatment and prevention. If design work is continued, we will engineer an optimal blower/motor combination that ensures efficiency and flexibility in the final design.

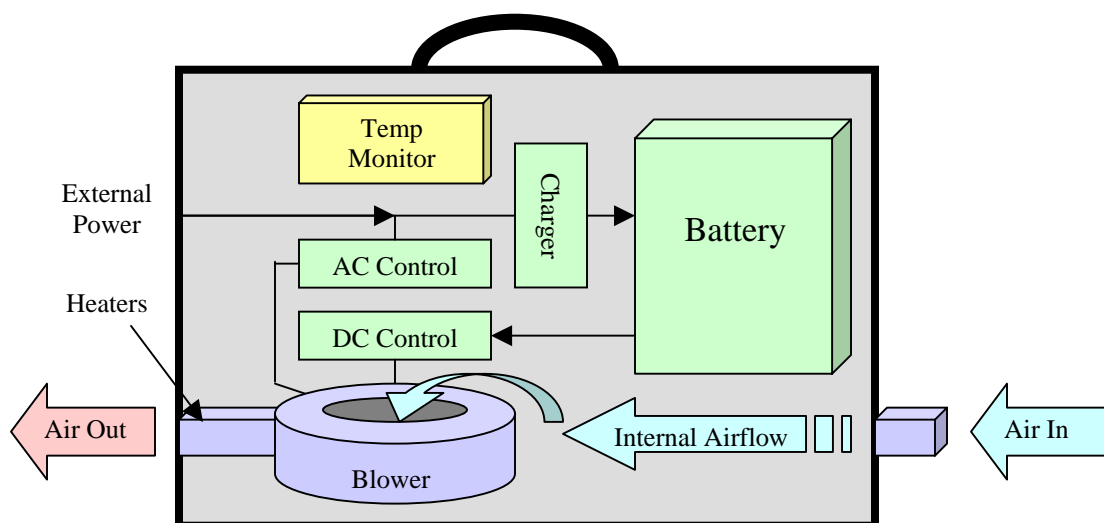


Figure 14: Internal schematic of Prototype warming unit

Batteries. The current prototype uses 4 Electrova³⁸ 160 watt-hour lithium ion batteries. These batteries were chosen for minimal weight, but they are expensive (\$400 ea). There are many other battery choices that are far more economical that should satisfy the navy's cost, weight, and volume requirements. As a result, the final battery selected may be significantly different from the one used in the prototype.

Using the Electrova batteries, the unit can provide 250W performance for 2 hours. However, in actual use many of the transport environments do not require 250W to prevent hypothermia and can be satisfied with much lower power levels. In that event, the unit has a far longer run time that is discussed in section 5.

Flexibility. Combat environments present many engineering challenges that require a great deal of design flexibility to overcome. Listed below are many of the design features that allow the unit to overcome these challenges:

- Control circuit redundancy. The unit contains fully independent control circuits that provide a level of redundancy. For example, if the DC circuit is damaged the unit can be run off its AC circuit using 110 VAC.
- Optional patient temperature control. If the patient is un-anesthetized, he or she can control the unit's temperature through a tethered cable remote.
- Adaptability to power supply. The unit can be charged on both 110 VAC and 24 VDC power.
- Over-temperature sensors and shutoff controls. This protects the patient from harm in the event that the heater locks into the on position.
- Low profile mounting method. The unit attaches to the litter under the patient's feet, allowing effective use with a minimal amount of obstruction.

5. To compare the design and performance of the prototype warming units to requirements gathered from the project monitor and expert users.

Approach

We have done ample in-house testing with human volunteers to discover the capabilities our device has to offer. In this section we discuss the results of a 2-hour practical test intended to mimic the environment found in aero medical transport.

Practical Testing

A volunteer test, conducted with a healthy, partially clothed, and awake individual, was completed in a simulated aeromedical transport environment. The patient was allowed to control the unit's output by remote, preferentially altering the incoming air temperature to maintain thermal comfort. As formerly stated, the power input to establish and maintain thermal comfort in an awake patient can be taken as a qualitative surrogate for the power that would be required to maintain normothermia in a sedated patient. The results of the test are shown in Figure 16.

As seen from the graph, the average ambient temperature, 7.6 °C, was similar to that encountered in an aeromedical transport environment, 10 °C. The only difference between the two environments would be found in the radiative losses, since the wall temperature of the plane (approx -10 °C) is much cooler than the wall temp (approx 10 °C) of our facility. However, by using a reflective mylar top (emissivity approx 0.05) the absolute value of the radiative losses in each environment become small enough that their differences are marginal in significance. For this equivalent test, the volunteer required an average power of 91 watts to retain thermal comfort over a two-hour period. The average temperature of air delivered to the blanket was 31.4 °C, which is lower than the temperature (37 °C to 43 °C) delivered to most convective warming blankets used to maintain normothermia in a hospital setting. This difference can be explained by noting that the skin exposure for patients under standard convective blankets is much greater than skin exposure under the insulated coverlet. As a result, a patient under a traditional convective blanket loses much more heat through exposed areas than a patient under the insulated coverlet. To make up for this disparity, the traditional convective blanket must use a greater delivery temperature to maintain normothermia. With a prototype warming unit battery supply of 640 watt-hours, the unit would be expected to function for 7 hours in an aeromedical transport environment.

Recirculation represented a major energy savings: instead of having to heat 7.6 °C ambient air to 31.4 °C, recirculated air at 26 °C was heated to 31.4 °C. This results in a 77% reduction in warming unit power requirements, meaning a unit using recirculation would require a battery ¼ of the size of the battery required for a unit without recirculation. Based upon the results of volunteer testing, it appears that the prototype unit-in its current form would satisfy many of the military's transport warming needs.



Figure 15. The interior of the warming unit.

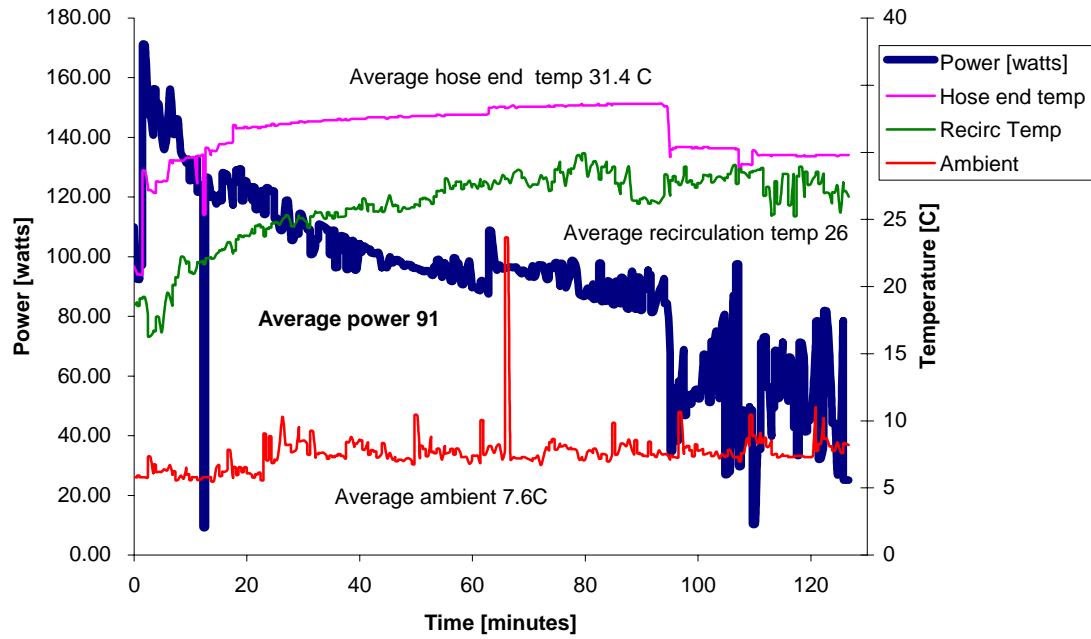


Figure 16: Volunteer temperature and power vs. time for aero medical transport environment test.

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IX. Budget Report

Arizant Healthcare – Topic N04-T021 – Proposal N045-021-0053

Budget - Expenditure Report 26-Jan-05

BUDGET				ACTUAL		Balance
Direct Labor						
Individual	Rate/Hour	Est. Hours	Cost	Hours	Cost	Balance
Senior Scientist	\$54	130	\$7,020	165	\$8,910	(\$1,890)
Design Engineer	\$30	150	\$4,500	155	\$4,650	(\$150)
Electrical Engineer	\$45	70	\$3,150	84	\$3,780	(\$630)
Design Engineer	\$43	70	\$3,010	80	\$3,440	(\$430)
Other Eng.	\$25			165	\$4,125	(\$4,125)
Other Eng	\$39			274	\$10,686	(\$10,686)
Subtotal Direct Labor Dollars			\$17,680		\$35,591	(\$17,911)
Overhead				Cost		Balance
% of Direct Labor Dollars		58%			\$20,643	(\$10,388)
Arizant Total Direct Labor			\$10,254		\$20,642.78	(\$10,388.38)
Direct Material Costs				Hours	Cost	Balance
Prototype materials			\$2,000		\$10,306.00	(\$8,306.00)
General lab supplies			\$1,289		\$1,959.00	(\$670.00)
Total Direct Material Costs			\$3,289		\$12,265.00	(\$8,976.00)
Other Direct Costs				Hours	Cost	Balance
Subcontr. (environmental chamber)			\$3,000		\$2,213.00	\$787.00
Travel to military customers			\$2,000		\$2,782.00	(\$782.00)
Other Direct Costs Total					\$4,995.00	\$5.00
Univ. of Minnesota – Topic N04-T021 Research Institute Cost						
BUDGET				ACTUAL		Balance
Univ. of Minn. student	Rate/Hour	Est. Hours	Cost	Hours	Cost	Balance
Eng Grad student (Ryan Barrows)	\$20	225	\$25,387	0.00	\$0.00	\$26,208.00
Subtotal Direct University Labor Dollars			\$25,387	0.00	\$0.00	\$0.00
Univ. overhead rate	Percentage	10%	\$2,539	0.00	\$0.00	\$0.00
Research institution total cost			\$26,208	0.00	\$0.00	\$0.00
Total Other Direct Costs			\$26,208	0.00	\$0.00	\$26,208.00
BUDGET				ACTUAL		Balance
Arizant General and administrative rate						
Individual	Rate/Hour	Est. Hours	Cost	Cost		Balance
Indirect Costs are calculated by taking total G&A pool dollars, divided by all other costs.						
G&A Pool \$ (see supporting data)			\$9,168,405			
% of All Fixed Mfg & Operating Expenses		0.16%	\$104	\$117.59		\$0
Total Cost before profit			\$64,815		\$73,493.78	\$6,848.62
Fee or Profit Rate		8%	\$5,185		\$5,879.50	
Estimated Budget			\$70,000			
Total Estimated Expenditure to date					\$79,373.28	\$6,849
Payment Schedule University of Minnesota						\$26,208.00
Not received		1st Invoice Jan-05		\$13,104.00		
Not received		2nd Invoice May -05		\$13,104.00		
Total						\$26,208.00